



PTO/SB/08A (10-01)

Approved for use through 10/31/2002. OMB 0851-0031

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~~Substitute for form 1449A/PTO~~

## **INFORMATION DISCLOSURE STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Substitute for form 1449A/PTO		Complete if Known	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> <i>(use as many sheets as necessary)</i>		Application Number	10/506,749
		Filing Date	27 June 2005
		First Named Inventor	Simon Michael Cutting
		Group Art Unit	1645
		Examiner Name	
Sheet	01	of	03
		Attorney Docket Number	2840-2

## **U.S. PATENT DOCUMENTS**

## **FOREIGN PATENT DOCUMENTS**

Examiner Signature	/Virginia Portner/	Date Considered	08/13/2007
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**EXAMINER:** Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04.

<sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

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PTO/SB/08B(10-01)

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>				Complete if Known	
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				Filing Date	27 June 2005
				First Named Inventor	Simon Michael Cutting
				Group Art Unit	1645
				Examiner Name	
				Attorney Docket Number	2840-2

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS				
Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.		T <sup>2</sup>
/GP/		Minton et al., Chemotherapeutic tumor... spores; FEMS Microbiology Reviews, Vol. 17, pages 357-364 (1995)		
		Casula et al., Bacillus Probiotics: Spore Germination ... Tract; Applied and Environmental Microbiology, Vol. 68, No.5, pages 2344-2352 (May 2002)		
		Duc et al., Bacterial Spores as Vaccine Veh.; Infection and Immunity, Vol. 71, No.5, pages 2810-2818 (May 2003)		
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		Ivins et al., Cloning and Expression...Bacillus Subtilis; Infection and Immunity, Vol. 54, No.2, pages 537-542 (Nov. 1986)		
		Ivins et al., Immunization against Anthrax...; Infection and Immunity, Vol. 58, No.2, pages 303-308 (Feb. 1990)		
		Hess et al., Superior efficacy of secreted ...against listeriosis; PNAS, Vol. 93, pages 1458-1463 (Feb. 1996)		
		Darji et al., Oral Somatic Transgene Vaccination...; Cell, Vol. 91, pages 765-775 (12 Dec 1997)		
		McBride et al., Protective efficacy of a recombinant protective antigen...; Vaccine, Vol. 16, No. 8, pages 810-817 (1998)		
↓		Grillot-Courvalin et al., Functional gene transfer from intracellular bacteria...; Nature Biotechnology, Vol. 16, pages 862-866 (Sept. 1998)		
/GP/		Higgins et al., Deliver of protein to the Cytosol of macrophages...; Molecular Microbiology, Vol. 31, No. 6, pages 1631-1641 (1999)		

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Information Disclosure Statement by Applicant <i>(use as many sheets as necessary)</i>				<i>Complete if Known</i>	
Sheet	03	of	03	Application Number	10/506,749
				Filing Date	27 June 2005
				First Named Inventor	Simon Michael Cutting
				Group Art Unit	1645
				Examiner Name	
				Attorney Docket Number	2840-2

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/GP/		Barnard <i>et al.</i> , Vaccination against Anthrax with Attenuated Recombinant Strains ...; Infection and Immunity, Vol. 67, No.2, pages 562-567 (February 1999)		
		Zegers <i>et al.</i> , Expression of the protective antigen of Bacillus anthracis...; J. Applied Microbiology, Vol. 87, pages 309-314 (May 1999)		
		Cohen <i>et al.</i> , Attenuated Nontoxinogenic and Nonencapsulated Recombinant...; Infection and Immunity, Vol. 68, No.8, pages 4459-4558 (August 2000)		
		Isticato <i>et al.</i> , Surface Display of Recombinant Proteins...; Journal of Bacteriology, Vol. 183, No. 21, pages 6294-6301 (November 2001)		
↓		Brossier <i>et al.</i> , Anthrax Spores Make an Essential Contribution...; Infection and Immunity, Vol. 70, No.2, pages 661-664 (February 2002)		
/GP/		Pilgrim <i>et al.</i> , Bactofection of Mammalian cells by Listeria monocytogenes...; Gene Therapy, Vol. 10, pages 2036-2045 (2003)		

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Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet

01

of

05

**Complete If Known**

Application Number	10/506,749
Filing Date	3 September 2004
First Named Inventor	Simon Michael Cutting
Group Art Unit	
Examiner Name	

Attorney Docket Number

1307-27

**U.S. PATENT DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code <sup>2</sup> (if known)			
/GP/		US- 5,633,973	07-09-1998	Piontek et al.	
		US- 5,604,127	02-18-1997	Nisbet et al.	
		US- 5,707,353	01-13-1998	Mazer et al.	
		US- 5,738,651	04-14-1998	Walton et al.	
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		US- 5,755,688	05-28-1998	Piontek et al.	
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		US- 5,921,855	07-13-1999	Mazer et al.	
		US- 5,968,569	10-19-1999	Cavadini et al.	
		US- 6,080,401	06-27-2000	Reddy et al.	
		US- 6,080,417	07-18-2000	Mehner et al.	
		US-			

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		Country Code <sup>3</sup> - Number <sup>4</sup> - Kind Code <sup>5</sup> (if known)				
/GP/		AU 00753327 B2	01-21-1999	Shu et al.		
		BG 00863614 B1	08-18-1999	<i>Note in English if partially considered</i>		
		CA 0 2 222 758 C	07-09-1998	Gaier et al.		
		CA 0 2 281 463 A1	02-26-2001	Zlotkin		
		DE 197 38 775 A1	03-11-1999	Gossner et al.		
		DE 297 20 542 U1	04-16-1998	Gossner et al.		
		EP 0 287 699 B1	10-26-1988	Iwanami et al.		
		EP 0 862 863 B1	09-09-1998	Cavadini et al.		
		EP 1 137 424 B1	10-04-2001	De Jong et al.		

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Substitute for form 1449A/PTO				<b>Complete If Known</b>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>				Application Number	10/506,749
				Filing Date	3 September 2004
				First Named Inventor	Simon Michael Cutting
				Group Art Unit	
				Examiner Name	
(use as many sheets as necessary)					
Sheet	02	of	05	Attorney Docket Number	1307-27

## **U.S. PATENT DOCUMENTS**

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		Country Code <sup>3</sup> - Number <sup>4</sup> - Kind Code <sup>5</sup> (if known)				
/GP/		FR 0 2 780 413 B1	12-31-1999	Lopez et al.		
		RU 2 114 536 C1	07-10-1998	Chernyshkov et al.		
		RU 2 134 993 C1	08-27-1999	Korochkin et al.		
		RU 2 149 008 C1	05-20-2000	Gaponyuk et al.		
		SK 280 832	12-18-1997	Dobias et al.		
V		WO 1993 014187 A1	07-22-1993	Adami et al.		
		WO 1998 026787 A1	06-25-1998	Conway et al.		
		WO 1998 047374 A1	10-29-1998	Farmer et al.		
/GP/		WO 1998 054982 A1	12-10-1998	Farmer et al.		

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Sheet	03	of	05	Attorney Docket Number	1307-27

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		Country Code <sup>3</sup> - Number <sup>4</sup> - Kind Code <sup>5</sup> (if known)				
/GPI		WO 1999 011542 A2	03-11-1999	Gossner et al.		
		WO 1999 028833 A1	08-17-1999	Wadström et al.		
		WO 1999 0041996 A1	08-28-1999	Wallenbeck		
		WO 1999 042560 A1	08-26-1999	Wallenbeck		
		WO 2000 07606 A2	02-17-2000	Farmer		
		WO 2000 010582 A2	03-02-2000	Farmer		
V		WO 2000 028007 A1	05-25-2000	Reddy et al.		
		WO 2001 013927 A2	03-01-2001	Farmer		
/GPI		WO 2001 015714 A1	03-08-2001	Zlotkin		

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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

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Sheet 04

of 05

**Complete If Known**

Application Number	10/506,749
Filing Date	3 September 2004
First Named Inventor	Simon Michael Cutting
Group Art Unit	
Examiner Name	

Attorney Docket Number 1307-27

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		Country Code <sup>3</sup> - Number <sup>4</sup> - Kind Code <sup>5</sup> (if known)				
/GP/		WO 2001 0085188 A1	11-15-2001	Dong et al.		

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/GP/		KAREN ROBINSON ET AL., <i>Oral Vaccination of Mice against Tetanus with Recombinant Lactococcus lactis</i> , July 1997, (5 pages), Volume 15, Nature Biotechnology, Cambridge UK			
		ADAM DRIKS, <i>Bacillus Subtilis Spore Coat</i> , March 1999, (20 pages), Volume 63, No. 1, Microbiology and Molecular Biology Review, Maywood, Illinois USA			
		ROBERTO M. LA RAGIONE ET AL., <i>Bacillus Subtilis spores competitively exclude Escherichia coli 070:K80 in poultry</i> , 17 August 2000, (10 pages) Veterinary Microbiology 2062, Surrey UK			
		TRAN THU HOA ET AL., <i>Fate and dissemination of Bacillus Subtilis Spores in a Murine Model</i> , September 2001, (5 pages), Vol. 87, No. 9, Applied and Environmental Microbiology			
		DAVID H. GREEN et al., <i>Characterization of Two Bacillus Probiotics</i> , September 1999, (4 pages), Applied and Environmental Microbiology			
		NGO THI HOA et al., <i>Characterization of Two Bacillus Species Used for Oral Bacteriotherapy and Bacterioprophylaxis of Gastrointestinal Disorders</i> , December 2000, (7 pages), Applied and Environmental Microbiology			

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